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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,876	12/12/2003	Howard T. Bellin	2003-2090.CON	1026

22476 7590 09/15/2004

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,876	BELLIN ET AL.	
	Examiner	Art Unit	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6692527. Although the conflicting claims are not identical, they are not patentably distinct from each other more broadly claiming the identical implant; see applicant's remarks filed 12/21/03 section G.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21, 26, 28, 33, 36 claim "said patch" which lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23 and 25-36 are rejected under 35 U.S.C. 102(b) as being anticipated by McGhan et al (3,852,832).

McGhan et al teaches a breast implant comprising a fillable "envelope" having one side having a relatively smooth surface and another side (comprising 12a, 12d, and 37) having a relatively rough surface to allow for tissue ingrowth. The implant, as clearly shown in figures 3-4, has a relatively thicker side comprising said relatively rough surface.

Note column 2, lines 53 et seq., teaching the implant is formed to a mold and then stripped leaving an aperture opening which is later closed by a closer 12d, interpreted as a patch.

Applicant claims "the envelope apart from the said patch is one-piece", however, claims the "envelope is sealed" inferring the patch is attached to the envelope forming a integral "one-piece" final product. McGhan et al also teaches an integral implant but formed form three-pieces; envelope 12a, closure 12d, and sheet 37. It is the Examiner's position that the final product of McGhan's et al fulfills all claim limitations.

Claims 28, 30, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker (5,026,394).

Baker teaches a breast implant comprising a fillable "envelope" having a relatively smooth anterior surface and a thicker posterior side 20, 14. Said implant envelope is sealed, and wherein the envelope apart from said patch 34, 72 is one piece.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGhan et al (3,852,832).

McGhan et al discloses the invention as described above. However, McGhan et al is unclear as to the rough surface being about 50 percent of the total surface. Lacking any criticality in the specification (see applicant's specification page 13, lines 5-14, teaching about 5-50 percent) the use of the rough surface being about 50 percent of the total surface in lieu of those used in the references solves no stated problem and would have been an obvious matter of design choice within the skill of the art. Additionally, it would have been obvious to one having ordinary skill in the to use more of the rough surface to increase the tissue ingrowth increasing securement of the implant as needed.

Claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prescott (5,522,896) in view of Baker (5,026,394).

Referring to figure 1B, Prescott teaches a breast implant comprising a fillable "envelope" having a relatively smooth anterior surface and a thicker posterior side comprising elements 4 and 6. Prescott teaches an additionally layer/coating 4 on a breast prosthesis:

"The prothesis of the present invention can also comprise a base material of predetermined shape, e.g., a conventional prosthetic device, and a layer of elastomeric material provided on the base material, wherein the layer of elastomeric material has distributed therein or provided thereon bio-active ceramic or glass particles (column 5, lines 34-39)."

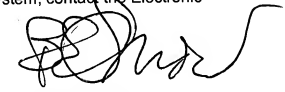
Inherently, a conventional prosthetic with an additionally coating, such as the breast implant such in figure 1B, would produce a thicker posterior side relative to the anterior side. It is noted that Prescott teaches the coating to increase tissue adhesion; see at least column 1, lines 29-38. The posterior surface with coating is relatively rough when compared with the anterior surface without a coating.

However, Prescott is silent regarding a patch. Baker teaches a "conventional prosthetic breast implant with a patch 34 or 72. It is would have been obvious to one having ordinary skill in the art to have utilized a patch as taught by Baker on the conventional implant of Prescott to close any hole due to manufacturing techniques, cuts, etc. It would have been obvious to one having ordinary skill in the art to have utilized the coating on the patch also if a posterior hole existed such that tissue adhesion would be maximized.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255.. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BRUCE SNOW
PRIMARY EXAMINER